REMARKS

Claims 1, 3-14, 17-19 and 20 – 27 have been cancelled without prejudice and claims 28 – 41 are now pending in the RCE. Support for the claims can be found in the specification of the pending application, U.S. Patent Publication No. 2007/0128292 as follows.

Table I: Support for Claims

Claim	Support (Paragraph No.)
28	0014
29	0014
30	0022
31	0022
32	0021 and Examples 1-3
33	0023 and Examples 1-3
34	0013
35	Table II
36	Table II
37	0022
38	0022
39	0022
40	0022
41	0022

Table II: Percentages of Various Components[1]

Component	α-linolenic acid	Eicosapentaenoic acid	docosahexaenoic acid	γ-linolenic acid
Example 1	900/1500 (60%)	100/1500 (6.7%)	270/1500 (18%)	115/1500 (7.7%)
Example 2	1000/1500 (66.7%)	80/1500 (5.3%)	300/1500 (20%)	
Example 3	800/1500 (53.3%)	100/1500 (6.7%)	300/1500 (20%)	
Example 4	800/1500 (53.3%)	100/1500 (6.7%)	200/1500 (13.3%)	

35 U.S.C. § 102(b) Rejections

The Examiner has rejected previously pending claims 1-2, 4-8,10 -11 and 15 under 35 U.S.C. § 102(b) as being anticipated by Nippon Oils (JP 03297364) and Yeo, U.S. Patent No. 5,312,834. In the Office Action, the Examiner stated that Nippon Oils teaches a pharmaceutical product containing at least 10% EPA and DHA and 20-30% ALA; according to the Examiner, Yeo teaches a pharmaceutical composition containing EPA and ALA. The Examiner noted that Yeo did not teach DHA.

As amended, independent claims 28 and 35 require α-linolenic acid ("ALA") eicosapentaenoic acid ("EPA"), docosahexanoic acid ("DHA") and an antioxidant at specific weights or precentages. Neither reference discloses all of the elements of the pending claims. Accordingly, the pending claims are not anticipated by either Nippon Oils or Yeo.

35 U.S.C. § 103(a) Rejections

The Examiner has rejected previously pending claims under 35 U.S.C. § 103(a) as being obvious. Specifically, the Examiner stated that the following claims were obvious:

[1] All ratios are mg/mg where the numbers are drawn from the Examples.

(i) claims 3, 9 and 13-14, Nippon Oils in view of Maingault (FR 2721517); (ii) claims 3, 6-7, 9 and 14, Yeo in view of Maingault; (iii) claims 1-8 and 10-16, Matsuura (U.S. Patent No. 5,756,088; and (iv) claim 9 Matsuura in view of Maingault.

(i) Nippon in view of Maingault - With respect to Nippon, the Examiner states that "Nippon does not teach the claimed amounts of ALA, EPA and DHA." Office Action, 8/7/08, pg 5. As amended now, the claims require specific weights or percentage ranges of ALA, EPA, DHA as well as the presence of an antioxidant (see, Claims 28 and 35). The Examiner states that Maingault teaches that "kiwi seed oil was known to be a rich source of ALA." Office Action 8/7/08, pg. 5. According to the title of the Nippon reference, the compositions are directed at antithrombogenic powders, while the Maingault art appears to be a dietary supplement for the maintenance of the brain and eyesight. Thus, the Applicant respectfully suggest that neither of these references teaches or suggests all of the claim limitations, nor would there have been any reasonable expectation of success when these references were combined and modified to achieve a formulation that could prevent or treat cardiovascular disease.

(ii) Yeo in view of Maingault - The Examiner states that "Yeo teaches a pharmaceutical composition comprising EPA and ALA", but "does not teach ... [adding] DHA." Office Action, 7/8/08, pg. 6. As noted above Maingault teaches that kiwi seed oil is a rich source of ALA. As amended, the claims require ALA, EPA, DHA and an antioxidant in specific ranges (see, Claims 28 and 35). Thus, not only would it have been necessary to modify the teachings of Yeo to add additional components, DHA and an antioxidant, but also, the ranges of fatty acids taught by Yeo fall outside the claimed ranges. Specifically, Yeo teaches that the "present invention provides a natural pharmaceutical composition which contains fish oil and perilla oil in various mixing ratios." (Yeo, Col. 4, lines 13-16). Examples, 1-4 of the Yeo patent disclose formulations contain ALA at percentages ranging from 33% to about 40%, whereas the formulations of the present application require at least 53.3% (w/w) (see, Table II). Yeo discloses pharmaceutical formulation containing much lower percentages of ALA for treatment of acne, while Maingault discloses a dietary supplement for children and adults. Thus, neither of these references

teaches or suggests all of the claim limitations, either specific components or ranges. Because the references are directed at either an acne treatment of dietary supplement there would not have been any reasonable expectation of success if the references were modified to develop a cardioprotective pharmaceutical formulation.

(iii) and (iv) Matsuura – The Examiner states that "Matsuura teaches nutriceutical compositions comprising GLA, ALA, EPA and DHA." Office Action, 7/8/08, page 7. Although "published subject matter is "prior art" for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of 04-1074 11 ordinary skill to make and use the invention. See, In re Kumar, 418 F.2d 1361 (Fed. Cir. 2005), citing Beckman Instruments, 892 F.2d at 1551. The Applicants respectfully point-out that Matsuura does not enable a formulation which contains about 800 mg to about 1000 mg of α-linoleic acid, from about 80 mg to about 120 mg of eicosapentaenoic acid, from about 250 mg to about 300 mg of docosahexanoic acid and an antioxidant (see, claim 1). Rather, Matsuura only discloses formulations containing γ-linolenic acid and biotin for treatment of dog and cat dermatosis (see, Matsuura, Col. 3, lines 50-65 and Col. 4, lines 1-15). Moreover, the concentration of poly-unsaturated fatty in the compositions of Matsuura is less than the lower limit claimed. Specifically, Matsuura discloses that the concentration of the poly-unsaturated fatty acid is 0.5-50% (wt%) (Col. 2, line 59), whereas, the claimed range for poly-unsaturated fatty acids is greater than 50%. This, Matsuura cannot render the amended claims obvious as it does not enable a composition having the claimed components within specific ranges. Even if Matsuura were to support such claimed ranges, one of ordinary skill in the art would not have been motivated to use such a high percentage of ALA since the art cited by the Examiner, Yeo, indicates that ALA ranging from 33% to 40% is effective in the treatment of acne (*supra*) and the disclosed condition in Yeo is a skin disorder.

CONCLUSION

Given the foregoing, Applicants respectfully submit that all pending claims are in condition for allowance. Favorable action is earnestly solicited.

Respectfully submitted,
Axinn Veltrop & Harkrider LLP

By: /Michael A. Davitz/

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Michael A. Davitz, M.D. J.D.
Reg. No. 47,519
Customer No. 67272
114 West 47th Street
New York, NY 10036
Tel.: (212) 728-2236